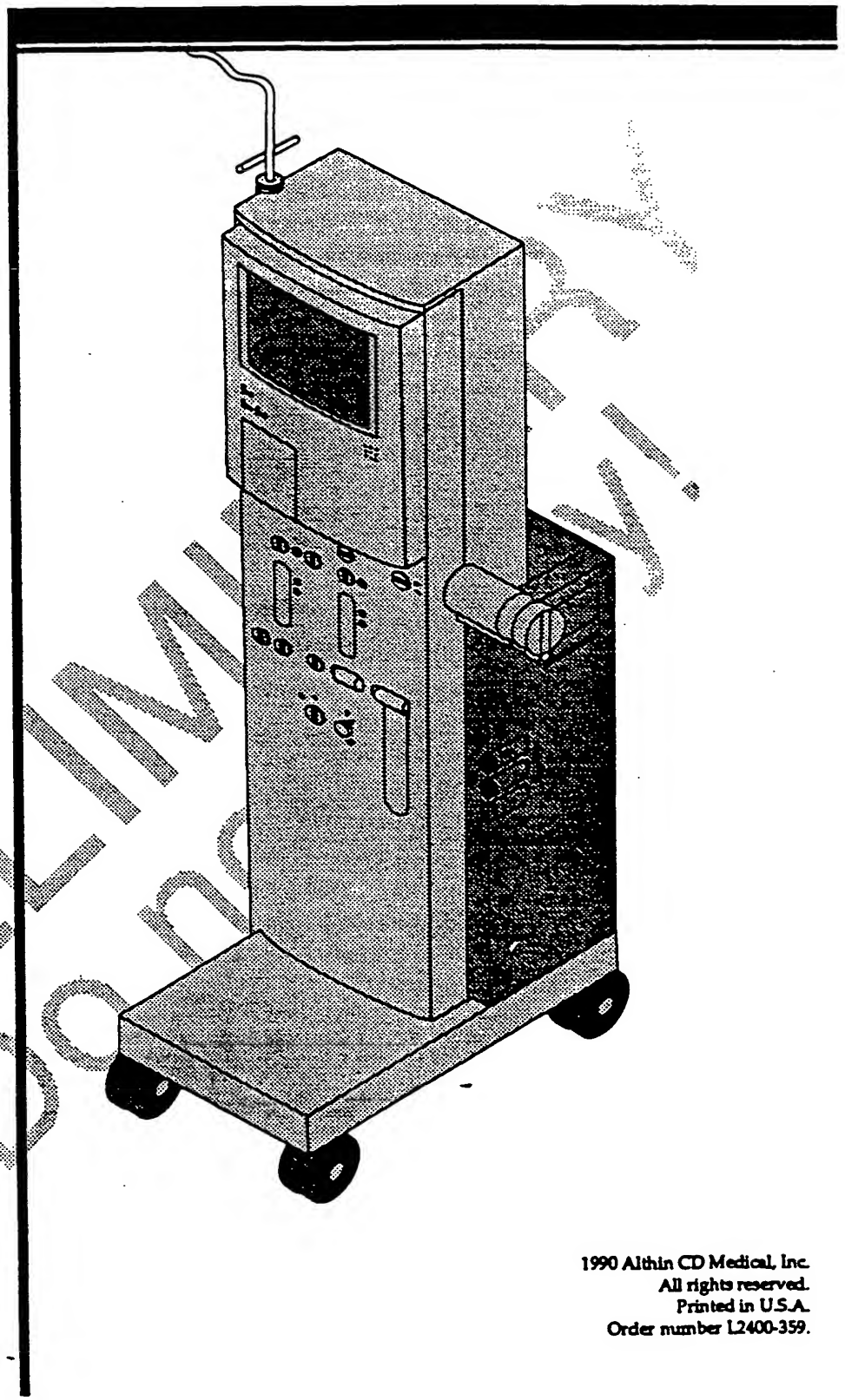
Drake Willock System 1000
Single Patient Delivery System
Maintenance Manual



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WARNING
This device is manufactured and intended for use only as prescribed by a physician. Modification, alteration, or lack of maintenance procedur s as described in the labeling, may adversely affect the safety and efficacy of this device. The manufacturer is not responsible for malfunctions that compromise patient safety as a result of alteration, neglect, or misus .

Replacement parts may vary from those shown in this manual. Should you have questions on those parts please contact Althin CD Medical, Inc.

The actual appearance of the machine may vary from the illustrations in this manual.

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Product Description

The Drake Willock ™ System 1000 is a single-patient hemodialysis delivery system, which will provide dialysate at the prescribed temperature and ionic concentration to be used for hemodialysis treatment. It will have the ability to monitor machine, dialysate and blood circuit functions during dialysis. The machine is based on volumetric proportioning, volumetric ultrafiltration and digital electronics. The machine and treatment parameters are displayed on a CRT (video monitor). The operator control is done through a interactive touch screen which also makes the machine very easy to clean and use.

The machine has an automated self test prior to the start of each dialysis, this ensures that all of the essential monitoring and alarm functions of the machine are tested before each patient treatment. The automatic self test eliminates the risk that a busy clinician will forget to perform the required machine checks prior to each treatment.

To enhance treatment quality assurance, the machine records essential treatment data such as actual treatment time. This actual treatment time clock stops when alarms interrupt dialysis by stopping the blood pump or bypassing the dialysate around the dialyzer. One of the major problems with the dialysis treatments given today is the non-delivery of the prescription (e.g.; the patient is taken off treatment 5 minutes early, repeated alarms stop the blood pump or divert the dialysate to drain stopping the treatment). The data report allows the operator of the machine to know the precise time spent on dialysis enabling the clinician to determine if the dialysis prescription was delivered.

Prerequisites

The service technician must:

- have a basic knowledge of electronics and hydraulics.
- have a basic knowledge of troubleshooting and preventive maintenance techniques.
- be thoroughly familiar with the contents of the operator's and maintenance manuals for this machine and all accessory devices that will be used with this machine.
- be sufficiently trained in the operation and maintenance of this machine and able to distinguish normal from aberrant machine behavior.

The System 1000 Single Patient Delivery System must:

- be in good working order and certified as such by the attending physician.
- be operated only in accordance with the machine specifications listed by Althin CD Medical and with the operating instructions contained within the System 1000 System Operator's Manual

and machine labeling. The attending physician is responsible for any changes to the procedures.

Indications

The System 1000 Single Patient Delivery System is indicated for use when a parallel flow dialyzer is chosen for use in chronic or acute hemodialysis treatments.

Contraindications

The System 1000 Single Patient Delivery System is not designed, sold or intended for any use except as indicated above. Furthermore, it is not intended to be used outside of the device specifications or limitations.

The System 1000 Single Patient Delivery System is not intended to be a substitute for the monitoring of the patient or of the patient's extracorporeal blood circuit by qualified personnel.

Product Improvement Policy

Drake Willock dialysis equipment was designed and built to the performance requirements stated in the product specifications.

It is the corporate policy to perform continuous product improvement research that often results in modifications to enhance patient safety or treatment effectiveness without incurring any obligation to make the same or similar changes to all equipment previously built and/or sold. When such improvements occur we will, from time to time, inform the owners of Drake Willock dialysis equipment and offer any available upgrades at reasonable prices. These upgrades, however, should not be construed as corrections of deficiencies, as the equipment met all the original product specifications when delivered.

Any product which, in the opinion of Althin CD Medical proves not to have met product specifications will be remedied by us.

Should pre-owned Drake Willock equipment be purchased and reconditioned, the equipment should not be used until testing and analysis demonstrate that the equipment meets the original or upgraded specifications.

Technical Support

Althin CD Medical offers technical support, technical training, consultation and machine service upon request. Contact your local Althin CD Medical service representative for additional information.

Maintenance Manual

This manual provides the qualified service technician with readily-available information regarding the Drake Willock System 1000 Single Patient Delivery System, its care, theory of operation and preventive maintenance. This manual includes information and instructions for all of the options of the System 1000 Single Patient Delivery System. Please disregard those sections of the manual that refer to features not in your machine.

This manual may be propped up for easy reference by opening the front cover then folding back the lower portion f the cover to form an easel.

A glossary of terms and abbreviations used in this manual is included in the Appendix.

Replacement Parts and Electrical Schematics manual packets are available upon request.

Safety Summary

This summary does not contain all the safety statements in this manual. Other warnings and cautions are included within the manual text.

Cautions

A CAUTION is a statement identifying conditions or practices that could result in equipment or other property damage.

Warnings

A WARNING is a statement identifying conditions or practices that could result in personal injury or loss of life.

WARNING **Maintenance should be performed by qualified service personnel only.**

WARNING **Federal law restricts this device to sale by or on order of a physician.**

WARNING **Do:**

- **read the operator's and maintenance manuals prior to servicing this machine.**
- **keep this and other associated manuals readily available for use by new operators or qualified service personnel.**
- **use the proper power cord.**
- **refer power cord changes to qualified service personnel.**
- **ensure that a qualified electrician or technician inspects the machine for proper electrical grounding at installati n before dialysis is initiated.**
- **disconnect power before removing protective panels, performing soldering, replacing components, or rem ving or replacing printed circuit boards.**
- **use fresh cleaning and disinfection chemicals.**
- **make sure that all modules are bolted together before moving the machine.**
- **unlock the wheels before attempting to move the machine.**

WARNING **Do not:**

- **under any circumstances perform any testing or maintenance of this machine while dialysis is in progress.**
- **cut or remove the round grounding prong from the plug.**
- **use any adapter device on the power cord for the purpose of plugging into a non-grounded power source.**
- **use an extension cord.**

WARNING **Do not:**

- **remove covers or panels when the machine is connected to a power source.**
- **operate the machine without covers and panels properly installed.**
- **remove any caution, warning or other descriptive labels from the machine.**
- **operate this machine in an explosive environment or near flammable anesthetics.**
- **perform internal service or adjustment of this machine unless another person capable of rendering first aid and resuscitation is present.**
- **touch exposed connections and components while power is supplied.**
- **use the I.V. pole as a handle for moving the machine.**

CAUTION

1. **Static discharge may damage electronic components.**
   - **Both MOS and Bipolar integrated circuits maybe damaged by discharge of static electricity.**
   - **Both digital and linear integrated circuits may also be damaged.**
   - **Static damage may occur not only to integrated circuits mounted on the circuit board, but also to detached integrated circuits.**
   - **Static damage may not be immediately evident.**
   - **Static damage is cumulative.**
2. **Do not remove or plug in any electronic component or assembly while power is applied to the machine.**
3. **Use only silicone base O-ring lubricant; other lubricants may damage the O-rings.**
4. **It is necessary to perform some of the adjustments with the covers removed. Use extra care to prevent fluids from entering or contacting the electronics of the machine.**

Machine Disinfection

Althin CD Medical, Inc. recommends the use only of disinfectants and cleaning agents that are specifically mentioned in the pertinent sections of this manual.

Other products on the market, besides the disinfectants we recommend, are being used with apparent success by some customers. Since these products may contain chemicals that might degrade or destroy components of the machines, or cause other problems, Althin CD Medical, Inc. assumes no responsibility for equipment damage resulting from the use of such products. The merits of each product should be evaluated by the user before purchase.

Althin CD Medical, Inc. will provide information upon written request regarding known machine incompatibilities with specific products.

WARNING **If alternate disinfectants are used, be sure to test the dialysate for residual disinfectant before each connection of a patient. Use a test method specific for the disinfectant and that is sensitive enough to produce accurate determinations of "safe" residual levels of disinfectant.**

Hydraulic Theory

Overview

The hydraulic system of the System 1000 hemodialysis machine is designed to heat incoming water to approximately human body temperature, mix it with dialysate concentrate in physiologically correct proportions and infuse it through an artifical kidney to effect hemodialysis therapy. In doing this, it also accurately measures the amount of fluid entering and exiting the artifical kidney and can adjust these volumes to control the fluid removal from the patient. Operation of the hydraulic components is controlled by a microprocessor.

Dialysate Circuit

Incoming Water Pressure Regulator

After entering the bottom of the hydraulic module the water pressure is reduced and stabilized by the water pressure regulator to the factory recommended level of 20 psi.

Water On/Off Valve

When power is on, the on/off valve opens to allow water to flow into the hydraulic circuit. When the power is off, the valve is closed preventing water from entering the machine.

Heat Exchanger

Heat is transferred from the effluent dialysate to the incoming water as the two liquids pass in counter current direction in adjacent heat exchanger compartments. This heat transfer preheats the incoming water, thus reducing the time the heater is on.

Heater, Thermistor, Safety Thermostat

The water is heated to the desired temperature by a 1500 watt heater. On the output of the heater is a thermistor. The thermistor acts like a variable resistor with changes in resistance being inversely proportional to changes in temperature. The thermistor sends a signal to the microprocessors, which then turns the heater on or off to maintain or increase the temperature.

Next to the heater is a thermostat which prevents the heater from exceeding a temperature of 130°C (266°F). The thermostat turns off power to the heater to prevent damage in case of a runaway temperature circuit failure.

"A" Concentrate Pump

The acid/acetate concentrate is pumped from its container int the air gap chamber through a fixed volume cam driven pump called the "A" concentrate pump. The pump uses a stepper motor that can be calibrated to a precise number of rotations per minute. A cam on the pump shaft moves a flexible diaphragm that delivers a fixed

volume of concentrate each rotati n. An optical sensor on the cam verifies the cam position for the microcontroller.

Using the dialysate flowrate and the concentrate information entered into the system by the operator, the microprocessor calculates the amount of concentrate necessary to achieve correct ratios of water and concentrate(s) for hemodialysis therapy. By adjusting the speed of the cam, the pump can be controlled to deliver a prescribed volume of concentrate. The pump will automatically compensate for changes in the dialysate flow rate in the event that the flow rate is changed during the procedure.

During Rinse, the "A" concentrate line is attached to the "A" rinse fitting and receives rinse water from this port.

In the disinfect mode, the "A" concentrate line is attached to the disinfectant rinse fitting and the "A" concentrate pump delivers disinfectant to the fluid path.

Supply Manifold

The supply manifold controls the incoming water flow, mixes the "A" dialysate concentrate component, removes most of the dissolved air from the water and monitors the "A" concentrate conductivity. The supply manifold is composed of four components: the supply valve/air gap chamber, the deaeration system, the air trap and the "A" conductivity probe. This manifold also contains the inlet for the "A" concentrate pump. The "A" concentrate pump is described in another section of the Hydraulic Theory.

The "A" and "B" rinse fittings connect through a common line to the supply manifoldand draw rinse water from this source.

Supply Valve/Air Gap Chamber

Heated water enters this chamber through a lever activated supply valve at the top of the cylinder. The lever mechanism is operated by a float in the adjacent air trap chamber. The float in the air trap chamber controls the flow of water into the hydraulic system by causing the air gap valve to open when the fluid level supporting the float drops and by closing the valve when the fluid level rises.

The volume of incoming water is determined by the quantity of water entering the flow equalizer. In normal operation, as the supply pump draws solution from the air trap chamber to fill the flow equalizer, the air trap float is pulled downward. Lowering the float causes the supply valve to open letting water flow into the air gap chamber during the fill cycle of the flow equalizer. When the flow equalizer is full and the supply pump no longer draws solution from the air trap, the fluid level in the air trap rises, causing the float to shut off the supply valve. This cycle is repeated during every fill phase of the flow equalizer.

The air gap at the top of this chamber is at atmospheric pressure and acts as a barrier to prevent the back flow of incoming water into the input line in the event of a drop in the incoming water pressure.

"A" Rinse Fitting

The "A" rinse fitting is located on the right side panel of the machine. This fitting is connected to the common channel of the supply manifold and uses this channel as the source of water for rinsing the "A" concentrate line. When the "A" concentrate line is attached and the power is on, this fitting supplies water to rinse the "A" concentrate line and "A" concentrate pump. During the rinse mode and when the machine is turned off, the "A" concentrate line is inserted into this fitting.

A proximity sensor built into the "A" rinse fitting senses when the "A"concentrate line is attached to this rinse fitting. Some machine functions such as the rinse cycle and the disinfect mode require specific input from this fitting before they may be activated. This input helps prevent misapplication of the equipment.

"B" Rinse Fitting

The rinse fitting for the bicarbonate line is located on the right side panel of the machine cabinet. This fitting is connected to the common channel of the supply manifold and uses this channel as the source of water for rinsing the "B" concentrate line. When the "B" concentrate line is not in use during acetate dialysis or during rinse, it is connected to its rinse fitting and recirculates the solution being proportioned.

A proximity sensor built into the "B" rinse fitting signals the microprocessor when the "B" concentrate line is in this fitting. Some machine functions such as the rinse cycle and the disinfect mode require specific input from this fitting before they may be activated. This input helps prevent misapplication of the equipment.

Deaeration System

The deaeration system is composed of the deaeration sprayer, the air removal pump and a loop that transfers the deaerated fluid from the deaeration sprayer chamber to the air trap chamber. The deaeration system is connected to the other supply manifold components by a common channel in the supply manifold. Its purpose is to remove the dissolved gases that are trapped in the water used to make up dialysate. If non deaerated water was allowed to circulate through the machine, these dissolved gasses would affect the accuracy of the fluid removal system.

The air removal sprayer facilitates the removal of air from the dialysate solution. The air removal pump moves fluid at approximately 1500 mL/min through the loop connecting it to the supply manifold and pulls the solution through the air removal sprayer nozzle at this rate. The sprayer nozzle restricts the flow so that a partial vacuum of approximately 500 mmHg is created in the air removal sprayer chamber. The water that passes through the air removal sprayer is deflected into a cone shaped spray pattern. This exposes a large surface area of water to a 500 mmHg vacuum. The vacuum decreases the concentration of air that the water can hold in solution and the large surface area increases the rate at which the air comes out of the water thus enhancing the air removal function.

Vented Air Trap

The purpose f the vented air trap is to allow air liberated by the deaeration sprayer to leave the system through a common channel at the top of the air gap and air trap chambers that is open to the atmosphere. This air trap also contains a float that helps control the flow of water into the system by means of the float /lever mechanism previously mentioned in the Supply Valve/Air Gap Chamber section.

The air removal pump loop delivers the de-aerated dialysate to the air trap chamber via a port slightly elevated from the bottom of the air trap chamber. This elevated port allows air bubbles may rise to the surface independent of the common fluid path.

"A" Conductivity Probe

Conductivity is usually defined as the ability of a solution to pass an electrical current. Measurement of the conductivity of the dialysate is used to determine that the solutions are being correctly proportioned based on the electrolyte composition of the product. The conductivity of dialysate will vary due to the temperature and the electrolyte composition of the dialysate concentrate used.

Two stainless steel electrodes positioned in the supply manifold flow path monitor the conductivity of the solution. A thermistor in one f the probes supplies the conductivity circuitry with information that is used to compensate for the effect temperature has on the conductivity reading.

The first conductivity probe ("A") in the flow path is located in the supply manifold before the "B" mix point. Tis probe measures the conductivity of the water and "A" concentrate only.

"B" Concentrate Pump

When using bicarbonate dialysis therapy, the bicarbonate concentrate is pumped from its container into the supply manifold through a fixed volume cam driven pump similar to the "A" concentrate pump. The pump uses a stepper motor that can be calibrated to a precise number of rotations per minute and a cam on the pump shaft to move a flexible diaphragm that delivers a fixed volume of concentrate per each rotation. An optical sensor on the cam verifies the cam position for the microprocessor.

Using dialysate flowrate and concentrate information entered into the system microprocessor by the operator, the microprocessor calculates the amount of concentrate necessary to achieve correct ratios for hemodialysis therapy. By adjusting the speed of the cam, the rate of flow through the pump cavity can be controlled to deliver a prescribed volume of concentrate in the ratio requested by the operator. Once it is set, the pump will automatically compensate for changes in the dialysate flow rate in the event that the dialysate flow rate is changed during the procedure.

During rinse, the concentrate motor operates at a nominal ratio of 1.8:34 and pumps 1 mL of rinse fluid to 34 mL of water to flush

concentrate or disinfectant from the concentrate pump chamber. In the rinse mode, the "B" concentrate line is attached to the "B" rinse fitting and receives rinse water from this port.

Supply Pump Recirculation Loop

The supply pump recirculation loop mixes the "B" concentrate component, monitors the total conductivity, regulates the pressure and pumps the solution to the flow equalizer. This loop contains the inlet for the "B" concentrate pump, bicarbonate mix chamber, the "B" conductivity probe, the supply pump, the supply regulator and a dialysate filter (optional.) The loop configuration helps to mix the bicarbonate concentrate by recirculating the solution through the "B" mix chamber. The loop also acts as a conduit for flow that is diverted by the pressure supply regulator at the end of each flow equalizer fill cycle.

"B" Mix Chamber

During hemodialysis therapy, the solution that enters the "B" mix chamber from the supply manifold contains water and acetate concentrate or water and the acid and bicarbonate components of bicarbonate dialysate. This chamber mixes the solution before it is monitored by the "B" conductivity probe.

"B" Conductivity Probe

The second conductivity probe in the flow path is located at the outlet of the "B" mix chamber in the dialysate supply recirculation loop. Two stainless steel probes in the flow path, one containing a thermistor to compensate for temperature differences, measure the the electrolytic content of the solution that leaves the "B" mix chamber.

The "B" probe monitors the total conductivity of the dialysate solution at this point in the flowpath. The conductivity circuitry subtracts the "A" conductivity probe reading from the "B" conductivity probe reading and compares the difference to the expected result based upon the concentrate formulation data entered by the operator. In the acetate therapy mode, the difference of this calculation should be zero and is used to recheck the "A" conductivity probe reading. When bicarbonate dialysis therapy is used, the microprocessor calculates the "B" portion of the solution and compares the result to the expected value for that concentrate formulation.

Conductivity measurements are affected by temperature and the thermistor gives the circuitry input for this variable. The thermistor in the "B" conductivity probe also supplies the input for the redundant high temperature alarm circuit.

Supply Pump

The supply pump has two functions. The first is to supply the flow and pressure to fill the flow equalizer with fluid. The supply pump operates at a fl wrate approximately 50 mL/min higher than the dialysate flowrate set by the operat r. This extra margin insures an

adequate supply of solution to fill the flow equalizer. It produces a pressure that is regulated to a maximum of 12.5 psi to propel the fresh dialysate into the flow equalizer.

The second function is to create a flow through the supply pump recirculation loop. When the flow equalizer reaches the filled state, the the pressure in the pressure regulator increases to a preset limit, causing it to divert solution into the recirculation loop. This creates a flow through the recirculation loop that helps mix the contents of the "B" mix chamber.

Dialysate Filter (optional)

The dialysate filter is used to stop any foreign material from reaching the flow equalizer.

Pressure Regulator

This back pressure regulator is set to approximately 16 psi. The solution flow is directed to the flow equalizer for filling the compartments. When the flow equalizer compartments reach the end of the fill cycle, pressure builds up in the supply loop. At approximately 16 psi the regulator opens up to allow solution to flow through the supply pump recirculation loop momentarily until the flow equalizer begins another fill cycle. Constant repetition of this pressure buildup and pressure valve operation creates a flow into the supply pump recirculation loop.

Input Pressure Equalizer

At the inlet of the flow equalizer is a pressure equalizer. This device along with the output pressure equalizer matches the relative pressure differences between the inflow and outflow of the flow equalizer so that the compartments fill and empty at an even rate.

The pressure equalizer is a chamber divided by a flexible diaphragm into two compartments. At the center of the diaphragm is a valve that is designed to fit into an outlet port on one side of the compartment. Solution from the supply pump recirculation loop flows unimpeded through the compartment without the valve and into the flow equalizer. The other compartment in the pressure equalizer contains solution flowing from the dialyzer to the effluent compartments of the flow equalizer and is also part of the dialysate pressure pump recirculation loop. This returning fluid is pressurized by the dialysate pressure pump.

The input pressure equalizer matches the pressure of the solution returning from the dialyzer/rinse block with the supply pump pressure filling the flow equalizer. Whenever this supply pump pressure is greater than the pressure generated in the other compartment by the dialysate pressure pump, the diaphragm forces the valve to restrict the flow of fluid in the pump recirculation loop. This causes an increase in the dialysate pressure that shortly matches the supply pump pressure. By forcing the pressure of the fluid in the dialysate pump recirculation loop to equal the supply pump pressure, the relative difference between these two pressures as measured in the flow equalizer is nearly equal and the flow equalizer fills at an even rate.

Flow Equalizer

The flow equalizer is made of two nearly identical chambers. Each chamber is comprised of tw compartments (one pre-dialyzer and one post-dialyzer), separated by a diaphragm and four solenoid actuated valves that control the filling and emptying of the compartments. The supply pump pressurizes the input to the pre-pump forcing it to fill. In phase 1 of the UF control cycle, while C-1 the pre-dialyzer compartment is filling with fresh dialysate the diaphragm separating it from the C-2 compartment transverses the cavity forcing an equal amount of effluent dialysate from the C-2 compartment to the drain. In this cycle , the amount of fresh dialysate entering the C-1 compartment is equal to the effluent dialysate in C-2 being displaced.

At the same time, effluent dialysate enters C-4 post-dialyzer compartment forcing the diaphragm to transverse the cavity, thereby pushing an equal amount of fresh dialysate out of the C-3 compartment to the dialyzer.

In phase 2, the solenoid valves which route the flow into and out of the flow equalizer package all turn off for a short period of time (125 msec). This valve shut-off time helps eliminate any significant effect on ultrafiltration accuracy that would result from two solenoid valves being open at the same time.

In phase 3, a different group of flow equalizer solenoid valves is then energized. This causes compartment C-2 to fill with effluent dialysate forcing the fresh dialysate in C-1 to flow toward the dialyzer. The C-3 compartment fills with fresh dialysate pushing the effluent dialysate in C-4 to flow to the drain. By balancing the flow of dialysate to and from the dialyzer, with two flow equalizer conpartments, the dialysate flow to the dialyzer can be accurately measured over a wide range of flowrates. After phase 3 is complete the solenoid valves on the UF diaphragm pump shut off again in phase 4 and then the whole cycle starts over again in phase 1.

Output Pressure Equalizer

At the exit of the diaphragm flow equalizer is another pressure equalizer. This device equalizes the pressure differences between the outflow of the pre and post equalizers, so that the diaphram cavities fill and empty at an even rate. Flowing on one side of the output pressure equalizer is the fresh solution going to the dialyzer. In the compartment on the other side is the fluid leaving the dialyzer and on its way to the drain.

The pressure equalizer is a chamber divided by a flexible diaphragm. At the center of the diaphragm, facing in opposite directions, are two valves. The valves are held by the diaphragm so that they are suspended above openings on either side of the chamber. Fluid enters each compartment formed by the diaphragm at the end of the chamber parallel to the diaphragm and exits through the openings on the side. When the pressure is equal on either side of the diaphragm, fl w through each compartment is unimpeded. When the pressure on one side of the diaphragm is

greater in relation to the other side, it causes the valve to restrict or occlude the opening on the side at the lower pressure. With its outlet blocked, incoming fluid increases the pressure until it equals the higher pressure on the other side of the diaphragm. This forces the valve to pen and normal flow t resume.

If pressure differences were allowed to persist, the compartments would empty at a rate determined by the pressure differences on either side of the dialyzer. These relative pressure differences could cause uneven emptying. By restricting the flow of the lower pressure fluid and forcing it to equalibrate with the higher pressure, the pressure equalizer ensures that the flow into and out of the pre and post flow equalizers will be at nearly equal rates

End Of Stroke Sensors

End of stroke sensors are located in the flow path at the inlet of the output pressure equalizer. These sensors verify when the flow equalizer compartments have reached the end of the fill cycle. When these compartments are full, the sensor sends a signal to the microprocessor, verifying that the compartments are full and the valve sequence must be changed. The open/close sequence of valves determines which compartments of the flow equalizer are filling and emptying.

Dialysate Monitoring Manifold

During hemodialysis therapy, the dialysate monitoring manifold checks the dialysate before it flows to the dialyzer and diverts unacceptable solution from the dialyzer. This manifold has two separate channels and contains: the final conductivity probe, a flow sensor and the dialysate pressure transducer. A loop containing the bypass valve connects the two channels such that solution leaving the channel with the conductivity probe must flow through the bypass valve before it reenters the second channel containing the flow sensor and pressure transducer.

Dialysate Conductivity Probe

The third conductivity probe is located in the manifold at the outlet of the output pressure equalizer. Composed of two stainless steel electrodes that protrude into the first channel in the manifold, this conductivity probe measures the total conductivity of the dialysate before it enters the artifical kidney. It compares the probes reading with the expected conductivity range based upon the concentrate formulation information previously entered by the operator. If the probe measures a value outside this range, its signal to the microprocessor activates the conductivity alarm and the bypass valve so that the solution is diverted to the drain and the operator is alerted.

Formulation information for the dialysate concentrate being used is entered into the machine's microprocessor by the operator. The conductivity circuitry processes this operator input and compares the monitored value with the expected range to determine if the system is functioning properly. If the conductivity is not within the

preset range, this information will cause the bypass valve to shunt the solution away from the artifical kidney and alert the operator.

A thermistor is built into one of the electrodes. The thermistor allows the conductivity reading to be electronically corrected by the microprocessor for temperature differences. This thermistor supplies information for the temperature display and the primary high and low temperature alarm limits.

This probe provides the conductivity information that is displayred to the operator on the CRT.

Flow Sensor

A flow sensor is located in the the second manifold channel and is used to monitor the fluid flow through that point. Similar to the nd of stroke sensor, the flow sensor contains a self heating variable resistor/thermistor. As current flows through the flow sensor it heats up. Being in the flow path, this element is cooled by the flow of fluid. When the flow flow stops, the sensor heats up, causing a change in the resisitance measured by the microprocessor. This change in the current through the thermistor due to the change in temperature tells the microprocessor that the flow has stopped. When the machine is in bypass, the lack of flow as measured by this sensor verifies the correct functioning of the bypass valve.

Dialysate Pressure Transducer

This pressure transducer senses the dialysate pressure and changes the pressure reading into an analog electrical signal proportional to pressure. This signal is used for the dialysate pressure display, alarms and control.

Bypass Valve

The bypass valve is located in a short loop that connects the conductivity probe channel of the dialysate monitoring manifold to the channel containing the flow sensor and the dialysate pressure transducer.

The bypass valve protects the patient in the event of a temperature or conductivity alarm by diverting unacceptable dialysate from the dialyzer. It is a 24 V dc three-way solenoid valve. During a dialysate temperature or conductivity alarm, an electronic signal causes the bypass valve to close the fluid path leading to the dialyzer. Instead the solution is shunted to a fluid path opening downstream from the dialyzer.

There is also a manual bypass mode that permits the operator to put the machine in bypass when a dialyzer is hooked up or sequential ultrafiltration therapy is performed.

Dialysate Sample Port

The sample port is provided as a opening for the operator to get a sample of the dialysate to test for conductivity or residual disinfectant. If dialysis in progress the dialyzer would be the next component in the flow path and this port all ws for sampling the

dialysate without interrupting the treatment. In the rinse mode, this port is used to test for disinfectant.

Dialyzer/Rinse Block

At this point in the fluid path the dialyzer is attached to the dialysate lines and is used to remove fluid and electrolytes from the patient. When the machine is not being used for a patient treatment and a dialyzer is not in use, the dialysate lines are attached to a rinse block. The rinse block allows the dialysate, rinse water or disinfectant to flow through the pre and post dialyzer lines.

Flow Sensor

Another flow sensor is located in the line leading the from dialyzer toward the dialysate pressure pump and is used to monitor the fluid flow through that point. The flow sensor contains a self heating variable resistor/thermistor. As current flows through the flow sensor it heats up. Being in the flow path, this element is cooled by the flow of fluid. When the flow stops, the sensor heats up, causing a change in the reisitance measured by the microprocessor. This change in the current through the thermistor due to the change in temperature tells the microprocessor that the flow has stopped. This flow sensor is used to check the UF system accuracy by monitoring the from dialyzer line during bypass to ensure that the flow equalizers are balanced and the flow has stopped.

Ultrafiltration System

The ultrafiltration system of the System 1000 machine allows the operator to remove a precise amount of fluid from a patient in a controlled manner. By controlling exactly how much dialysate is going to and returning from the dialyzer, accurate fluid removal is achieved. The main components of the UF system are the flow equalizer, the pressure equalizers, the dialysate pressure pump, the UF flow regulator, the UF flow meter, and the dialyzer.

Dialysate Pressure Pump Recirculation Loop

The dialysate pressure pump recirculation loop is located downstream from the dialyzer. It carries effluent dialysate from the dialyzer to the the flow equalizer. It also helps equalize the pressure differences in the compartments of the flow equalizer. A third function is to generate the pressure necessary to fill the UF flow meter. It contains; the dialysate pressure pump, the UF removal regulator, the UF flow meter, a sample port and the input pressure equalizer.

Dialysate Pressure Pump

The dialysate pressure pump is located in the dialysate flowpath. It operates in a loop that allows it to circulate fluid at a constant flow rate of 1500 mL/min without affecting the rate of fluid flow through the machine. By controlling the amount of fluid entering and leaving this loop, the dialysate pressure pump is used to change the pressure differences across the dialyzer membrane. The pressure and flow generated by this pump is also used to fill the UF flow meter and to fill and equalize the pressures in the flow equalizer.

The dialysate pressure pump circulates fluid through the dialysate pressure pump recirculation loop at a rate higher than the rate of flow through the machine. As long as this pump receives adequate volume, it will not affect the fl w dynamics f the main flowpath. When fluid is removed from this loop, the pump will attempt to replace it by demanding more volume from the main flowpath. Since the flow equalizer keeps the volume of dialysate going to and from the dialyzer constant, the only fluid available must come from the dialyzer. By precisely controlling the amount of fluid removed from the loop, the operator can control the amount of fluid removed from the patient via the dialyser.

The fluid pumped by the dialysate pressure pump is restricted by a flow restriction. This restriction provides sufficient pressure to the input of the removal regulator for normal operation.

The flow and pressure generated by the dialysate pressure pump is also used to fill the post dialyzer chambers in the flow equalizer. Through the dialysate pressure pump recirculation loop outlet in the input pressure equalizer this pump causes the flow equalizer compartments to fill when the valves open to let in fluid.

UF Removal Regulator

The dialysate pressure pump forces solution through the UF removal regulator. This regulator regulates the pressure at the input to the UF Flow Meter. This pressure is used to fill the UF Flow Meter.

UF Flow Meter

The UF flow meter is a measuring device composed of a precisely measured chamber with a small diaphragm separating it into two compartments. Each compartment has a three-way valve connecting it to the flowpath and to the drain. The UF flow meter is connected into the flowpath in the dialysate pressure pump recirculation loop between the dialysate pressure pump and the flow restriction and via the UF removal regulator. The dialysate pressure pump is restricted by the flow regulation and creates a positive pressure at this point which is regulated by the UF removal regulator that is used to fill the UF flow meter. A compartment fills when the microprocessor opens its valve to this positive pressure environment. When one compartment is filling, its companion compartment is emptying to the drain. Based upon knowing what volume is removed every time a compartment is opened, the microprocessor can measure precise amounts of fluid by sending a calculated number of open/close signals per minute to the valves. The rate of fluid removal is determined by the ultrafiltration information entered into the microprocessor by the operator. The microprocessor calculates the number of times per minute each valve must open to equal this UF volume.

When fluid leaves the system through the UF flow meter, less fluid is recirculated through the dialysate pressure recirculation loop. The volume f fl w that leaves through the UF fl w meter starves the input of the dialysate pressure pump by an equal amount. The

starved negative pressure pump creates the necessary pressure to remove an amount of fluid from the dialyzer equal to the fluid removed from the system through the UF flow meter.

The flowpath from the fresh dialysate compartments of the flow equalizer to the dialyzer and back to the effluent compartments of the flow equalizer is a closed system except for two openings. One opening is the dialyzer. The other is the UF flow meter. When the volume in the dialysate pressure recirculation loop is reduced by solution being remove through the UF flow meter, a negative pressure is exerted on the dialyzer. As long as the ultrafiltration rate of the dialyzer is sufficient to remove the volume being demanded, an equal amount of fluid will be removed from the patient. Thus the operator can enter a predetermined fluid removal rate into the machine and the machine will automatically remove it from the patient.

Blood Leak Detector

Effluent dialysate expelled from the flow equalizer passes through and is monitored for the presence of blood in the blood leak detector. There is a light source and a photocell monitoring the light transmitted through the solution present in the cavity. If blood leaks through the dialyzer membrane, the blood passing through the blood leak detector will absorb a portion of the light, preventing it from reaching the photocell. The dimmed light then sets off a blood leak alarm protecting the patient by stopping the blood pump, clamping the venous line and warning the operator.

Heat Exchanger

The effluent solution is circulated through the heat exchanger on its way to the drain so that the incoming water may benefit from a transfer of heat and be warmed by this fluid.

Rinse Valve

The rinse valve connects to the fluid path immediately after the flow sensor on the downstream side of the dialyzer. When the System 1000 machine is in rinse, the microprocessor forces the UF flow meter to remove rinse fluid from the dialysate pressure recirculation loop at approximately 4 L/h to insure adequate flushing of this component. Since the flow equalizer maintains the closed loop configuration during the rinse and disinfect cycle, fluid must be added to the system at this point to replace the volume lost through the UF flow meter. The rinse valve allows fluid to flow into the pressure pump recirculation loop from the drain line. When this valve is activated, the drain line fluid replaces the volume removed by the UF flow meter.

Extracorporeal Circuit

The components described in this section are presented in the approximate order in which they appear in the extracorporeal circuit.

Blood Pump

The blood pump is a peristaltic pump that moves extracorporeal blood at the prescribed flow rate during dialysis. During extracorporeal alarms, the blood pump stops, occluding the pump segment of the arterial blood tubing. Blood pump tubing with blood pump segment inter-diameters of 1/4-inch, 6-mm, 7-mm and 8-mm may be used with the blood pump.

A blood pump cover interlock switch prevents the blood pump from operating unless the cover is fully closed. The blood pump alarm will activate if the pump stops or overspeeds.

Venous and Arterial Pressure Monitors

The monitors indicate pressures in the extracorporeal drip chambers.

Connected to the venous and arterial monitors is a small motor operated peristaltic pump, this pump is used to raise or lower the level of blood in the extracorporeal blood line drip chambers

Heparin Pump

The heparin pump is a syringe pump that infuses heparin into the blood flow circuit at an operator-adjustable rate. The heparin pump alarms when the motor is infusing heparin faster than the setting on the device. It also alarms when the heparin syringe is empty or the motor is stalled.

Air Detector

The air detector continuously monitors the blood flow for the presence of air bubbles in the venous blood line.

The air detector is comprised of two ultrasonic transducers, one for transmitting, the other for receiving. Whenever a single air bubble or tight cluster of air bubbles of sufficient size passes between the transducers, some of the focused ultrasonic energy that would otherwise be received by the other transducer is scattered or obstructed. The resulting drop in signal at the receiving transducer triggers an air detector alarm.

During an air detector alarm the audio alarm sounds, the blood pump stops and the line clamp occludes the venous blood line. The UF rate slowly goes to zero. The blood and dialysate pressures will slowly equalize across the dialyzer membrane.

Line Clamp

The line clamp occludes the venous blood line during an extracorporeal alarm.

Heat Cleaning

The following three conditions *must* be met in order to start the Heat Clean Mode:

- The machine is in the Rinse Mode.
- There is a low conductivity alarm.
- The **HEAT CLEAN** button is pressed.

When the Heat Clean Mode is initiated, the following occur:

- The heat clean valve is opened.
- The flow rate is lowered to 370 ml/min.
- The air removal pump speed is lowered by 2/3.
- The desired "dialysate" temperature is set to 85°C (97°C at the heater output).
- **HEAT CLEAN** is displayed in the machine status area.
- The **HEAT CLEAN ABORT** button appears.
- The blood pump, UF removal system and concentrate pumps operate as in the Rinse Mode.

Since the flow signal used for the supply pump flow rate servoing (end-of-stroke signal) is lost at higher temperatures, the supply pump is locked after approximately 3 minutes of elapsed heat clean time.

When the temperature at the dialyzer connectors is greater than 70°C, the bypass valve is controlled using the state of the rinse interlock information. If the interlocks are not met, the bypass valve will be in the bypass state to prevent the possible exposure of the operator to hot water.

The time required for the fluid path temperature to reach values required for disinfection (80 to 85°C) is largely dependent on the operating conditions of the machine when the Heat Clean Mode is initiated. If the "dialysate" temperature is above the low temperature alarm limit at the start of Heat Clean, the time required to reach 85°C at the dialyzer connectors is less than 30 minutes.

The heat clean state is put into the cool down mode after an 85°C primary conductivity probe temperature has been held for at least 15 minutes*. The cool down mode will operate at the machine calibrated maximum flow rate until the primary high temperature alarm has ceased. When the primary temperature is out of alarm, the machine will revert back to the Rinse Mode. This cool down mode requires only 10 minutes at a flow rate of 800 ml/min.

The **HEAT CLEAN ABORT** button permits the operator to manually start the cool down mode.

* Reference Modern Microbiology by Wayne Umbeit, 1962.

Preventive Maintenance

This section describes routine maintenance, calibration and adjustment procedures required for proper care of the System 1000 machine. Local environmental conditions such as inadequate water quality or the need for additional procedures such as routine acid flushes may require shorter periods between maintenance. As each maintenance procedure is completed, record the date and the type of maintenance in a log.

The System 1000 machine has been thoroughly factory-tested; fine adjustments however may be necessary prior to clinical use. If further adjustments are necessary they should be referred to a qualified service person.

Before any adjustments or calibrations are made, the system should be allowed to warm up for at least 10 minutes.

When maintenance is completed, perform a full functional check of the system. Ensure that the machine has been disinfected before returning it to clinical use.

Recommended Maintenance Schedule

With every maintenance of the machine:

Check and repair, replace, adjust or tighten as required:
- Hydraulic leaks
- Worn parts
- Loose parts and connections
- Discolored wires, terminals, relay contacts, and tubing
- Improperly seated circuit boards and modules
- Electrical connections
- Corroded valves

As required:

Clean:
- External surfaces
- Concentrate and disinfect line rinse ports and rinse block

Every month:

Rinse:
- Fluid path with vinegar

Every 3 months:

Clean:
- Fluid path with bleach
- Blood leak detector

Calibrate:
- Blood leak detector

As required or at least once a year:

Check/adjust:
- Blood pump occlusion

Every 6 months:

Perf rm all functional checks (per this manual):
Calibrate if necessary

Every 12 months:

Check:
Line cord ground continuity

As required:

Replace:
O-rings
Dialysate filter
Concentrate filters
Tubing
Lamps
Worn/defective parts
Level adjust tubing

Before prolonged storage:

Disinfect and drain:
Fluid path

Supplies

Cleaning Supplies:

- Clean, dry cloths
- Basin
- Household bleach (5.25% sodium hypochlorite)
- Mild detergent solution (such as mild dishwashing detergent in water)
- Diluted bleach solution (4 parts fresh household bleach and 126 parts cold water); for example, 40 mL fresh household bleach and 1260 mL cold water
- Vinegar (5% acetic acid solution), (i.e., clean fresh white vinegar)
- pH color indicator strips, range pH 6 to 8

Test/Calibration Tools:

- Pressure test gauge, 0 to 30 psi
- Pressure test gauge, 750 to –750 mmHg
- Timer or stop watch
- Blood line set of the type to be used in therapy
- Syringe, 10 to 20 mL capacity (The type used for heparin infusion.)
- Syringe, approximately 50 mL capacity
- Three way stopcock
- Dialysate concentrate solution
- Electronic scale, minimum 3 kg capacity with 0.1 gram readability
- One liter capacity beaker
- Bucket with minimum 4 L capacity
- Temperature probe assembly with in-line monitoring capability, scale accurate within ±0.2°C in a 30 to 50°C range
- In-line conductivity meter
- Tube occluding forceps

CAUTION

1. Static discharge may damage electronic components.
   - Both MOS and Bipolar integrated circuits maybe damaged by discharge f static electricity.
   - Both digital and linear integrated circuits may als be damaged.
   - Static damage may occur not only to integrated circuits mounted on the circuit board, but also to detached integrated circuits.
   - Static damage may not be immediately evident.
   - Static damage is cumulative.
2. Do not remove or plug in any electronic component or assembly while power is applied to the machine.
3. Use only silicone base O-ring lubricant; other lubricants may damage the O-rings.
4. It is necessary to perform some of the adjustments with the covers removed. Use extra care to prevent fluids from entering or contacting the electronics of the machine.

WARNING

1. Do not under any circumstances perform calibrations or testing of this machine while dialysis is in progress.
2. Disconnect power before removing protective panels, soldering, replacing components, or replacing printed circuit boards.
3. Use care when servicing the machine with power on or the machine plugged in.
4. Dangerous voltages exist at several points in the machine. To avoid personal injury, do not touch exposed connections and components while power is applied.
5. Servicing the CRT requires thorough knowledge of the shock hazard and handling precautions associated with this type of component.
6. Do not perform internal service or adjustment of this machine unless another person capable of rendering first aid and resuscitation is present.
7. If maintenance is to be performed after the machine has been used for dialysis, ensure that the fluid pathway has been cleaned.
8. Before performing any maintenance on the hydraulic system, turn off the power and the water.
9. After maintenance is completed, perform a complete functional test of the machine before returning it to clinical use.

10. **After maintenance is completed, disinfect the machine with formaldehyde before returning it to clinical use. Allow formaldehyde to remain in the system for at least two hours.**

11. **Do not exceed the maintenance intervals given in the schedule or neglect to perform the maintenance as recommended.**

Note

Refer to the "Safety Summary" section of this manual for other applicable information.

Unless otherwise noted, perform all dialysate circuit calibrations and adjustments with the machine operating under normal dialysis conditions (i.e., solution temperature at 38°C and within normal conductivity range).

Before opening the dialysate fluid pathway for maintenance, make sure the water supply is off.

Cleaning Procedures

Clean Fluid Path With Bleach

WARNING **If maintenance is to be performed after the machine has been used for dialysis, ensure that the fluid pathway has been cleaned.**

Supplies

- 200 mL household bleach (5.25% sodium hypochlorite)
- Small beaker, approximately 500 mL capacity.

Precondition

- Patient disconnected.
- Machine has been rinsed for at least 10 minutes with water.
- Machine is in rinse mode.

Procedure

1. Connect the disinfect line (yellow connector) to a container of 200 ml of household bleach.
2. Connect the acid/acetate concentrate line (pink connector) to the disinfect rinse port (yellow).
3. Allow diluted bleach to infuse into the fluid path for 15 minutes.
4. After the 15 minutes, disconnect the machine from the bleach supply.

   To disconnect the machine:

   a. Connect the acid/acetate concentrate line (pink connector) to the acid/acetate rinse port (pink).

   b. Wait approximately 15 seconds for the disinfect line to drain, then connect the disinfect line (yellow connector) to the disinfect rinse port (yellow).

CAUTION **Do not allow bleach to remain in the fluid path longer than the recommended time or damage may result.**

5. Rinse the machine for approximately 30 minutes. Continue rinsing until a test specific for the presence of sodium hypochlorite is negative.

6. Turn off the power switch and water supplyx.

Rinse Fluid Path with Vinegar

Overview

To remove bicarbonate precipitate (insoluble calcium carbonate deposits) from the machine fluid path. Bicarbonate precipitate is a white to cream-colored deposit formed downstream of the bicarbonate mixpoint. Other precipitates and/or discolorations will not be removed by following this procedure.

It is important to follow this vinegar rinse procedure. If allowed to accumulate excessively, bicarbonate precipitate can cause problems with operation of the equipment.

This procedure will not prevent bicarbonate precipitate formation; it is only useful in controlling accumulation of the deposit. Perform this procedure as often as conditions indicate.

Supplies

- Vinegar (5% acetic acid solution)
- pH color indicator strips, range pH 6 to 8

Precondition

- Patient disconnected.
- Machine in rinse mode, rinsing with water.
- Dialysate flow rate is 1000 ml/min.

Procedure

1. Check the pH of the rinse water using a pH indicator strip. This will establish a baseline pH value to which the system should be rinsed after exposure to the vinegar.
2. Connect the disinfect line to the container of vinegar.
3. Connect the acid/acetate concentrate line to the disinfect rinse port.
4. Infuse approximately 800 ml of vinegar into the fluid path. This will take approximately 30 minutes.
5. Before the vinegar supply is completely exhausted, turn off the machine.
6. Allow the vinegar to remain in the fluid path for approximately 30 minutes. For high precipitate build-up allow 60 minutes.
7. Meanwhile, remove the acid/acetate concentrate line from the disinfect port
8. Remove the disinfect line from the vinegar supply and connect the line to the disinfect rinse fitting.
9. After the 30 minute dwell time, turn on the machine and start rinse.
10. Set the dialysate flow rate to 1000 ml/min.
11. Rinse the fluid path for at least 15 minutes.

12. Inspect the dialysate lines. If precipitate is still present, an infusi n of another fresh supply f vinegar is required; repeat steps 2 through 10. If the lines are clean, go to the next step.
13. Using pH indicator strips, check the pH of the rinse water.
14. Continue rinsing as required until the pH of the rinse water has returned to the value noted in step 1, above.

Clean Blood Leak Detector

Supplies

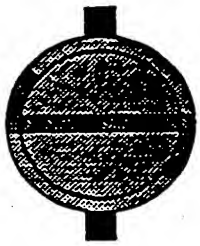
- Clean, dry cloths
- Basin
- Mild detergent solution (such as mild dishwashing detergent in water)
- Diluted bleach solution (4 parts fresh household bleach and 126 parts cold water); for example, 40 mL fresh household bleach and 1260 mL cold water
- Cotton swabs
- O-ring lubricant

Preconditions

- Fluid path cleaned.
- Machine off.
- Water supply off.

CAUTION **Handle the sensors with care. Do not drop or allow them to get wet.**

Procedure

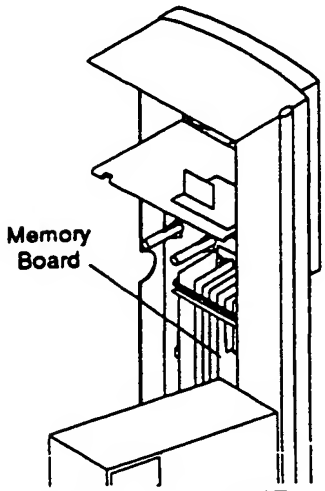


Blood leak detector

1. Locate the blood leak detector on the back of the machine.
2. Remove the detector cover by rotating and pulling it toward you.
3. Clean the inside of the detector tube and the inner side of the detector cover.
4. Apply a thin film of O-ring lubricant on the end cap O-ring. Do not allow O-ring lubricant to get on the lenses.
5. Reinsert the cover by aligning it with the grooves and pushing as you turn to engage it.
6. Recalibrate the blood leak detector before returning the machine to clinical use.

Calibration/Adjustment Procedures

Overview



System 1000 with CRT cover removed to expose printed circuit boards

The System 1000 has a menu driven calibration mode. When the calibration mode is activated, on-screen prompts help inform the technician of the proper actions necessary to complete each calibration test/check. The manual contains the step by step procedure for calibrating the machine.

Technician actions involve collecting and measuring dialysate flow, ultrafiltrate and concentrate fluids; sampling temperature and conductivity; adjusting pump pressures; and inputting the results of these actions as instructed by the on-screen messages.

During normal operations, the operator does not have access to the calibration mode. An internal switch *must* be activated and the machine restarted to obtain the calibration mode. The calibration mode contains buttons that select individual tests and display instructions for completing the tests. If technician inputs are not within the expected range, a screen message alerts the technician.

When the calibrations are completed, the machine *must* be returned to the operational mode by turning off the calibration switch and restarting the machine using the mains power switch.

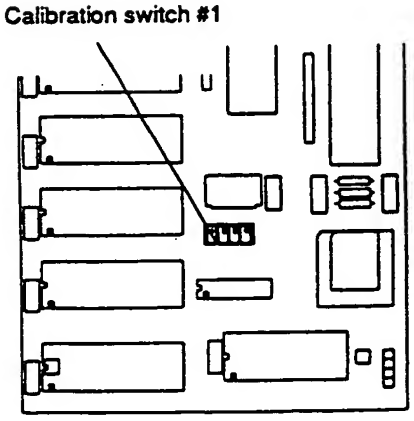
To Activate the Calibration Mode

Preconditions

- Power cord is plugged into the wall socket.
- Power switch is off.
- Hydraulic Module is open.

Procedure

1. Turn off the mains power switch.
2. Remove the splash shield covering the mother board and its associated boards.
3. Locate the memory board attached to the third slot from the right on the mother board bus. The memory board is identifiable by the large ribbon cable connected to the top of the board.
4. Locate the board component near the lower end of the memory board containing four small switches.
5. Push calibration switch #1 (closest to the rear of the machine) into the on position.
6. Reinstall the splash shield.
7. Turn on the mains power switch to reactivate the touch screen. It is not necessary to turn on the power switch.
8. When the screen is activated, touch the small dots that appear in sequence in the corners of the screen as instructed by the on screen message.



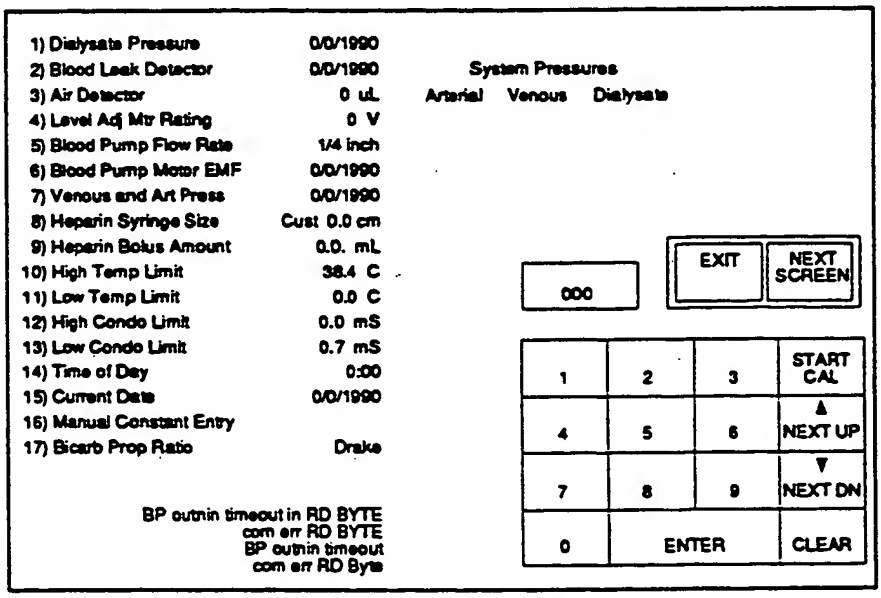
Memory board

9. When calibration screen #1 appears, touch the NEXT SCREEN button to activate calibration screen #2 if the following calibration procedures will be performed in order. Otherwise access the appropriate calibration screen for the calibration to be performed.

To Deactivate the Calibration Mode

1. Repeat above procedure through step 4.
2. Push the memory board calibration switch to the off position.
3. Replace the splash shield and close the Hydraulic Module.
4. Make sure the Operator screen appears upon the next machine start up.

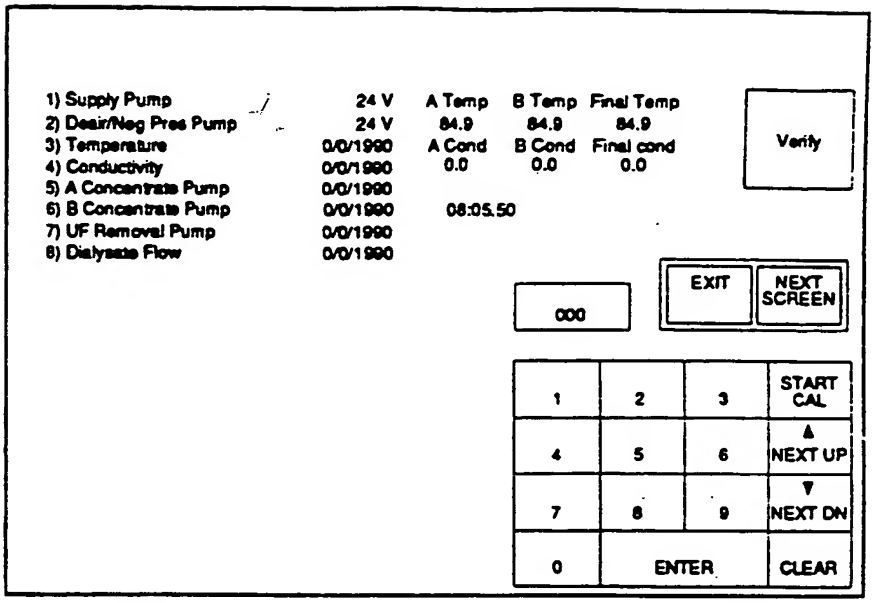
Note — Upon turning on the mains power switch, the machine will become fully activated without the need of turning on the power switch.



Calibration screen #1

Calibration Screen Guide

- To select a calibration line on the screen touch the **NEXT UP** or **NEXT DOWN** button until the desired is highlighted.
- To start a calibration procedure, select the desired test and touch the **START CAL** button.
- To stop a calibration procedure, touch the **STOP CAL** button.
- Th **STOP CAL** button replaces the **START CAL** button whenever a calibration procedure is in progress.
- To access the other calibration screen, touch the **NEXT SCREEN** button.
- To enter a number, touch the appropriate numbers on the keypad and then touch the **ENTER** button twice.
- T correct an erroneous keypad entry, touch the **CLEAR** button.
- T put the machine into the operator mode, touch the **EXIT** button.
- A **VERIFY** button will appear when needed in a procedure.



Calibration screen # 2

Calibrate Input Water, Deair Pump and End-of- Stroke Pressures

Supplies

- Pressure test gauge (0 to 30 psi)
- Pressure test gauge (750 to -760 mmHg)

Preconditions

- Water supply is on.
- Power switch is on.
- Hydraulic Module is open.
- Calibration screen #2 is displayed.
- Machine is in the rinse mode and has rinsed for at least ten minutes.

Procedure

Note — Pressure calibrations *must* be performed with the machine at a 1000 mL/min dialysate flow rate and the pressure relief (rinse?) valv open. Selecting the **DEAIR/NEG PRESS PUMP** calibration line will put th machine in this operating condition.

Note — When inputting numerical information onto the touch screen calibration display, enter the number using the keypad then touch the **ENTER** button twice to enter data.

1. Select the **DEAIR/NEG PRESS PUMP** calibration line and press the **START CAL** button.
2. Calibrate the input water pressure as follows:
   a. Connect a pressure gauge (0 to 30 psi) to the input water test port on the input water pressure regulator.
   b. The input water pressure should be 8 ±1 psig.

c. Adjust the input water pressure regulator as required until the pressure gauge indicates 8 ±1 psig.

d. Disconnect the pressure test gauge.

3. Calibrate the deair pressure pump as follows:

a. Connect a pressure test gauge (750 to -760 mmHg) to the test port in the line from the deair sprayer to the deair pump.

Note

At the bottom of the screen, the machine will prompt the user to enter the next deair pump voltage to be tested. At the top of the screen, the machine will prompt the user to verify the voltage entered when the deair pressure is correct.

b. Using the calibration keypad, enter a deair pump voltage that produces a deair pressure of 500 ±15 mmHg and touch the ENTER button twice.

c. Disconnect the pressure test gauge.

Note

After the deair pump voltage is entered, the VERIFY button will be visible on the screen.

d. If additional pressures are to be calibrated, do not press the VERIFY button at this time.

If calibrating only the input water and deair pressures, press the VERIFY button and deactivate the calibration mode.

WARNING **Before resuming patient dialysis therapy, be sure the calibration switch is in the off position.**

4. Calibrate the End-of-Stroke Pressure:

a. Connect a pressure gauge (0 to 30 psi) to the input pressure regulator on the side that is connected to the supply regulator.

b. The end-of-stroke pressure should be 16 ±1 psig.

c. Adjust the supply regulator as required until the pressure gauge indicates 16 ±1 psig.

d. Disconnect the pressure test gauge.

e. Complete the deair pressure calibration by pressing the VERIFY button.

f. Make sure the voltage printed on the deair pressure calibration line is the same value that was entered above.

Note

The next calibration procedure will be performed while the machine is operating in the Rinse Mode. All operation and calibration modes ar accessible when the memory board calibration switch is on and there is no need to deactivate the calibration mode at this time if more calibrations are planned. Before resuming patient dialysis therapy, be sure the calibration switch is in the off position.

5. Calibrate the UF Removal Pressure:

a. Press the EXIT button initiate the Operator Mode.

b. Initiate the Rinse Mode.

1) Press the RINSE then RINSE VERIFY buttons.

2) Make sure that RINSE is displayed in the machine status window.

c. Connect a pressure gauge (750 to -760 mmHg) in the line between the UF removal regulator and the UF removal metering device.

d. The UF removal pressure should be 200 to 300 mmHg.

e. Adjust the UF removal regulator as required until the pressure gauge indicates 200 to 300 mmHg.

f. Remove the pressure test gauge.

Calibrate Concentrate Pumps and UF Removal Metering Device

Note: The concentrate pump and UF removal metering device calibrations may be performed concurrently if the necessary scales and beakers are available.

Supplies:

- 1 to 3 electronic scale(s) (Minimum of 3 liter capacity with a 0.1 gram readability)
- 1 to 3 one liter beaker(s)
- Ultrafiltrate line port plug

Preconditions

- Mains switch is
- Power switch is off.
- Hydraulic module open.
- Calibration switch is on.
- Calibration screen #2 is displayed.

Procedure

1. Calibrate the acid/acetate concentrate pump:
   a. Select the A CONCENTRATE LINE calibration line.

Note: Removal of the concentrate line fitting prevents inaccuracies caused by water being unevenly retained by this fitting.

   b. Remove the fitting from the end of the acid/acetate concentrate line.

   c. Fill a 1 L beaker about half full of water.

   d. Place the acid/acetate concentrate line in the breaker of water, press the START CAL button and press the VERIFY button.

   e. Allow the concentrate pump to pump water from the one liter beaker until all visible signs of air have been removed from the concentrate line

   f. After the air has been cleared press the STOP CAL butt n.

Note: Be sure to remove the concentrate line from the beaker when instructed to. Removing this line at the appropriate time increases the accuracy of the measurement.

   g. Wait until the concentrate pump has stopped, then remove the acid/acetate concentrate line from th breaker of water. Place the beaker f water n the scale and tare the scale.

Tare the scale:
Zero the scale with the beaker of water at the beginning of a calibration so that th weight indicated on the scale is only the w ight of the water that was added to or removed from the beaker.
Refer t your scales instructions for detailed actions.

h. Place the acid/acetate concentrate line in the beaker of water, press the START CAL button and press the VERIFY button.

Note

An on-screen message will appear to count down the pump strokes.

i. Wait until 100 pump strokes have been completed as indicated by a pump stroke message printed on the screen.

j. The calibration system will then prompt the technician for the weight removed from the beaker.

   1) Remove the concentrate line from the beaker.

   2) Place the beaker of water on the scale and note the weight.

   3) Enter the weight from the scale onto the calibration keypad and press the ENTER button twice.

k. Repeat the above procedure (clear air from concentrate line only if needed).

l. If both weights are within 1% of each other, enter the weight from the scale onto the calibration keypad and press the ENTER button twice.

   If both weights are not within 1%, repeat the calibration.

   If the third calibration weight is within 1% of either of the first two calibration weights, enter the weight from the scale onto the calibration keypad and press the ENTER button twice.

   If the third calibration weight is not within 1% of either of the first two calibration weights, remove the machine from clinical service and consult the "Troubleshooting" section of this manual for further help.

m. Replace the fitting on the end of the acid/acetate concentrate line.

n. Connect the acid/acetate concentrate line to the acid/acetate rinse port.

3. Calibrate the bicarbonate concentrate pump:

   a. Select the B CONCENTRATE LINE calibration line.

Note

Removal of the concentrate line fitting prevents inaccuracies caused by water being unevenly retained by this fitting.

   b. Remove the fitting from the end of the bicarbonate concentrate line.

   c. Fill a 1 L beaker about half full of water.

   d. Place the bicarbonate concentrate line in the breaker of water, press the START CAL button and press the VERIFY button.

   e. Allow the concentrate pump to pump water from the one liter beaker until all visible signs of air have been removed from the concentrate line.

f. After the air has been cleared press the STOP CAL button.

Note

B sure to remove the concentrat line from th beaker when instructed to. Removing this line at the appropriate tim incr ases the accuracy of the measurement.

g. Wait until the concentrate pump has stopped and then remove the bicarbonate concentrate line from the breaker of water. Place the beaker of water on the scale and tare the scale.

h. Place the bicarbonate concentrate line in the beaker of water, press the START CAL button and press the VERIFY button.

Note

An on-screen message will appear to count down the pump strokes.

i. Wait until all 100 pump strokes have finished as indicated by the pump count message printed on the screen.

j. The calibration system will then prompt the user for the weight removed from the beaker.

1) Remove the concentrate line from the beaker.

2) Place the beaker of water on the scale and note the weight.

3) Enter the weight from the scale onto the calibration keypad and press the ENTER button twice.

k. Repeat the above procedure (clear air from concentrate line only if needed).

l. If both weights are within 0.1% of each other, enter the weight from the scale onto the calibration keypad and press the ENTER button twice.

If both weights are not within 0.1%, repeat the calibration.

If the third calibration weight is within 0.1% of either of the first two calibration weights, enter the weight from the scale onto the calibration keypad and press the ENTER button twice.

If the third calibration weight is not within 0.1% of either of the first two calibration weights, remove the machine from clinical service and consult the "Troubleshooting" section of this manual for further help.

m. Replace the fitting on the end of the bicarbonate concentrate line.

n. Connect the bicarbonate concentrate line to the bicarbonate rinse port.

4. Calibrate the UF Removal Metering Device:

a. Select UF REMOVAL PUMP calibration line.

b. Place the ultrafiltrate line in an empty 1 L beaker and make sure that a plug is placed on the ultrafiltrate line port to prevent air leaks through this port.

c. Press the START CAL button, then the VERIFY button.

d. When all the air has been cleared from the line press the **STOP CAL** button.

Not — Be sure to remov the ultrafiltrate line from the beaker when instructed to. Removing this line at the appropriate tim increases the accuracy f the measurement.

e. Remove the ultrafiltrate line from the beaker and tare the scale with the beaker on the scale.

f. Place the ultrafiltrate line in the beaker, press the **START CAL** button and press the **VERIFY** button.

Note — An on-screen message will appear to count down the UF removal device strokes.

g. Wait until the UF removal device has completed 100 strokes (stroke count is printed on the screen).

Note — Be sure to remove the ultrafiltrate line from the beaker when instructed to. Removing this line at the appropriate time increases the accuracy of the measurement.

h. The calibration system will then prompt the user for the weight pumped into the beaker.

   1) Remove the ultrafiltrate line from the beaker.

   2) Place the beaker of water on the scale and note the weight.

   3) Enter the weight from the scale onto the calibration keypad and press the **ENTER** button twice.

i. Repeat the above procedure (clear air from removal line only if needed).

j. If both weights are within 0.1% of each other, enter the weight from the scale onto the calibration keypad and press the **ENTER** button twice.

   If both weights are not within 0.1%, repeat the calibration.

   If the third calibration weight is within 0.1% of either of the first two calibration weights, enter the weight from the scale onto the calibration keypad and press the **ENTER** button twice.

   If the third calibration weight is not within 0.1% of either of the first two calibration weights, remove the machine from clinical service and consult the "Troubleshooting" section of this manual for further help.

Calibrate Flow Equalizer

Supplies

- Electronic scale (Minimum of 3 liter capacity with a 0.1 gram readability)
- 4 L capacity bucket

Preconditions

- Water supply is on.
- Power switch is on.

- Calibration screen #2 is displayed.
- Machine is in the rinse mode and has rinsed for at least ten minutes.

Procedure

1. Select the **DIALYSATE FLOW** calibration line.
2. Place an empty 4 L bucket on a scale and tare the scale.
3. Press the **START CAL**, then **VERIFY** buttons.
4. Move quickly with the tared bucket to the drain line and upon the next End of Stroke place the drain line in the pre-tared bucket.
5. The calibration system will then count 20 dialysate flow cycles. At the end of the 19th cycle, the machine will prompt the technician with an audible beep and a screen message to remove the drain line from the bucket at the next End of Stroke.

   Press the **VERIFY** button and wait at the drain to remove the line from the bucket upon the next End of Stroke.
6. After the next end of stroke (20th dialysate flow cycle), remove the drain line from the bucket.
7. The calibration system will then prompt the user for the weight increase of the bucket.
   a. Place the bucket on the original scale.
   b. Enter the weight from the scale onto the calibration keypad and press the **ENTER** button twice.
8. Repeat the above procedure.
9. If both weights are within 0.1% of each other, enter the weight from the scale onto the calibration keypad and press the **ENTER** button twice.

   If both weights are not within 0.1%, repeat the calibration.

   If the third calibration weight is within 0.1% of either of the first two calibration weights, enter the weight from the scale onto the calibration keypad and press the **ENTER** button twice.

   If the third calibration weight is not within 0.1% of either of the first two calibration weights, remove the machine from clinical service and consult the "Troubleshooting" section of this manual for further help.

Calibrate Dialysate Temperature

Supplies

- Temperature probe assembly with in-line monitoring capability (scale accurate within ±0.2°C in a 30 to 50°C range)

Preconditions

- Power switch is on.
- Machine is operating in the calibrate mode.
- Calibration screen #2 is displayed.

- All panels are in place on the machine.
- Hydraulic module is closed.

Not — Temperature calibration *must* be performed with all pan ls in place and the hydraulic module closed to stabilize the internal temperature.

Note — Always check the calibration date on the temperature probe to ensure that the calibration is current.

Procedure

1. Select the **TEMPERATURE** calibration line.
2. Press the **START CAL** button. The calibration system will then prompt the user to place a temperature probe in the dialysate line.
3. Place the temperature probe in the dialysate line at the Hansen connectors and press the **VERIFY** button.
4. The calibration system will then adjust the temperature to approximately 30°C and when stable prompt the user to enter the measured temperature. This process takes approximately 15 minutes.

   Enter the measured temperature into the calibration keypad and press the **ENTER** button twice.
5. The calibration system will then adjust the temperature to approximately 40°C and when stable it will prompt the user to enter the measured temperature. This process takes approximately another 15 minutes.

   Enter the measured temperature into the calibration keypad and press the **ENTER** button twice.
6. The temperature calibration is complete after the heigher temperature (~40°C) is entered into the calibration keypad. The flow rate will then change back from 1000 to 500 ml/min and the desired temperature will then revert back to 37°C. (Approximately 10 minutes is needed for the temperature to equilibrate.)

Calibrate Dialysate Conductivity

Supplies

- Dialysate concentrate solution normally used
- In-line dialysate conductivity meter

Note — Always check the calibration date on the conductivity probe to ensure that the calibration is current.

Preconditions

- Water supply is on.
- Power switch is on.
- Machine is displaying calibration screen #2.
- Temperature calibration was performed within the last two weeks.

N te — Th calibration routin requires that the temperature calibration was performed within the last two weeks or the conductivity calibration will not be allowed.

1. Select the CONDUCTIVITY calibration line.
2. Press the START CAL button. The calibration system will then prompt the user to place a conductivity probe in the dialysate line. Use a conductivity probe that has been recently calibrated.
3. Place the conductivity probe in the dialysate line and press the VERIFY button.
4. Place the acid/acetate concentrate line in a container of acetate dialysate concentrate. The calibration system will then proportion the concentrate and when the conductivity is determined to be stable the calibration system will prompt the user for the measured conductivity.
5. Enter the measured conductivity onto the calibration keypad and press the ENTER key twice.
6. The acid/acetate concentrate pump will continue to proportion concentrate and the three displayed conductivities will n w be calibrated from the previous procedure.

Set Supply Pump Voltage *Rating*

Preconditions

- Water supply is on.
- Power switch is on.
- Machine is in the calibration mode.

Procedure

1. Select the SUPPLY PUMP calibration line.
2. Press the START CAL button. The calibration system will then prompt the user to enter the supply pump voltage rating.
3. Use the keypad to enter an "18 V" voltage rating and press the ENTER button twice.
4. Make sure the voltage rating entered appears on the calibration line.

Calibrate Dialysate Pressure

Supplies

- A syringe (approximately 50 cc capacity)
- A stopcock (3-way)
- Pressure test gauge (750 to –760 mmHg)

Preconditions

- Water supply is on.
- Power switch is on.
- Machine is displaying calibration screen # 1.

Procedure

1. Select the DIALYSATE PRESSURE calibration line.
2. Press the START CAL button. The calibration system will then prompt the user to open the dialysate sample port to atmosphere. Open the sample port (double check that the

sample port is open to atmosphere) then wait a few seconds before pressing the VERIFY button.

3. After the VERIFY button has been pressed and the coarse dialysate pressure offset has been determined by the calibration system, it will prompt the user to pressurize the dialysate line to a negative pressure and then measure the pressure.
4. Use a stopcock, a syringe, and a pressure meter to pressurize the dialysate line to a stable and known pressure. Press the VERIFY button upon the proper pressure stabilization and measurement.
5. The calibration system will prompt the user for the negative dialysate pressure (a negative sign will appear in the calculator window). Enter the pressure on the calibration keypad and press the ENTER button twice.
6. The calibration system will then prompt the user to pressurize the dialysate line positive and take a measurement. Repeat the procedure explained in step 4 for a positive pressure and press the VERIFY button
7. The calibration system will then prompt the user for the positive dialysate pressure. Enter the pressure on the calibration keypad and press the ENTER button twice.
9. The calibration is complete at this point and the dialysate pressure should be verified.

Calibrate Venous and Arterial Pressures

Supplies

- A stopcock (3-way)
- Tubing with two female luer connectors attached
- Pressure test gauge (750 to –760 mmHg)

Preconditions

- Blood tubing set of the type used for hemodialysis is installed on the machine.
- Power switch is on.
- Calibration switch is on and the calibration screen #1 is displayed.

Procedure

1. Use the UP or the DOWN button to select the VENOUS AND ART PRESS calibration line.
2. Press the START CAL button. The calibration system will then prompt the user to open the blood circuit to atmosphere. Remove the transducer protectors and tubing from the venous and arterial pressure luers on the front of the machine and press the VERIFY button.
3. After the VERIFY button has been pressed, the calibration system will prompt the user to pressurize the blood circuit to a positive pressure and then measure the pressure. Use a piece of tubing with a female luer fitting n one end (to be connected to the arterial pressure fitting on the front of the machine) and a

fitting on the other end which will provide two female fittings when assembled (one of the fittings is to be connected to the machine and the other is to have a pressure test gauge connected to it).

4. After the two pressure fittings on the front of the machine are connected together and to a pressure gauge the level adjust buttons can be used to pressurize the blood circuit under test.
5. When a pressure of greater than 300 mmHg is achieved and is determined to be stable (if not stable and leaks are present fix the leaks before the calibration is completed, the STOP CAL button can always be pressed to abort any active calibration). Enter the measured arterial and venous pressures on the calibration keypad and press the ENTER button twice.
6. The calibration is complete at this point and the venous and arterial pressures should now be verified using the same procedure.

Calibrate Blood Pump EMF

Preconditions

- Blood tubing set of the type used for hemodialysis is installed on the machine.
- Power switch is on.
- Calibration switch is on and the calibration screen #1 is displayed.

Procedure

1. Select the BLOOD PUMP MOTOR EMF calibration line.
2. Press the START CAL button. The calibration system will then rotate the blood pump at a speed of about 60 RPM for about 10 seconds. After which point the calibration will be complete.
3. Note that the date printed on the BLOOD PUMP MOTOR EMF calibration line is the current date.

Calibrate Blood Leak Detector

Preconditions

- Blood tubing set of the type used for hemodialysis is installed on the machine.
- Power switch is on.
- Calibration switch is on and the calibration screen #1 is displayed.

Procedure

1. Select the BLOOD LEAK DETECTOR calibration line.
2. Press the START CAL button. The calibration system will then calibrate the blood leak detector in less than 3 seconds.
3. Note that the date printed on the BLOOD LEAK DETECTOR calibration line is the current date.

Operator Specified Calibrations

Prec nditi ns

- Water supply is n.
- Power switch is on.
- Machine is displaying calibration screen #1.

Note

The calibration settings listed in this section are operator specified and are dependent on clinical practices and procedures specified by the attending physician such as heparin syringe size, heparin bolus amount, blood tubing size, high and low temperature alarms and high and low conductivity alarms. The settings must be within the ranges specified or included in the listing of options below or else the screen will not accept them.

1. Calibrate the remaining System 1000 machine settings as follows:

a. Select the associated calibration line.
b. Press the **START CAL** button.
c. Enter the appropriate value.
d. Press the **ENTER** button twice.

2. Upon completion of this procedure, deactivate the calibration mode.

WARNING **Before resuming patient dialysis therapy, be sure the calibration switch is in the off position.**

The calibration setting ranges and options to be entered for the clinical System 1000 machines are listed below:

AIR DETECTOR	5 to 25 µL
LEVEL ADJ MTR RATING	12 V (fixed)
BLOOD PUMP FLOW RATE	6, 7 and 8 mm; 1/4 inch; and custom sizes
HEPARIN SYRINGE SIZE	Monoject 12 and 20cc, Becton Dickinson 10 and 20cc
HEPARIN BOLUS AMOUNT	0.5 and 1.0cc.
HIGH TEMP LIMIT	37 to 42°C
LOW TEMP LIMIT	29 to 37°C
HIGH CONDO ALARM	13 to 19 mS/cm
LOW CONDO LIMIT	9 to 14 mS/cm
BICARB PROP RATIO	DRAKE